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PFIZER INC., PHARMACIA CORPORATION, AND
G.D. SEARLE LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

19 IN RE CELEBREX AND BEXTRA) MDL Docket No. 1699
20 MARKETING, SALES PRACTICES AND)
21 PRODUCTS LIABILITY LITIGATION) CASE NO. 3:08-cv-1558-CRB
22 *This document relates to*)
23 CURT CARLSON,)
24 Plaintiff,)
25 vs.)
26 PFIZER, INC., PHARMACIA CORPORATION,)
27 and G.D. SEARLE LLC,)
Defendants.)
PFIZER INC., PHARMACIA CORPORATION, AND G.D. SEARLE LLC'S ANSWER TO COMPLAINT
JURY DEMAND ENDORSED HEREIN

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiff's Complaint as
2 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC
3 ("Searle") (collectively "Defendants"), and file this Answer to Plaintiff's Complaint
4 ("Complaint"), and would respectfully show the Court as follows:

I.

PRELIMINARY STATEMENT

7 The Complaint does not state in sufficient detail when Plaintiff was prescribed or used
8 Bextra® (valdecoxib) (“Bextra®”). Accordingly, this Answer can only be drafted generally.
9 Defendants may seek leave to amend this Answer when discovery reveals the specific time
10 periods in which Plaintiff was prescribed and used Bextra®.

II.

ANSWER

Response to Introduction

14 Answering the unnumbered paragraph preceding Paragraph 1 of the Complaint,
15 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
16 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law
17 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
18 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
19 developed, tested, marketed, co-promoted, and distributed Bextra® in the United States to be
20 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
21 with their approval by the FDA. Defendants admit, as indicated in the package insert approved
22 by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of
23 osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary
24 dysmenorrhea. Defendants state that Bextra® was and is safe and effective when used in
25 accordance with its FDA-approved prescribing information. Defendants state that the potential
26 effects of Bextra® were and are adequately described in its FDA-approved prescribing
27 information, which was at all times adequate and comported with applicable standards of care
28 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this

1 paragraph of the Complaint.

2 **Response to Allegations Regarding Jurisdiction and Venue**

3 1. Defendants state that this paragraph of the Complaint contains legal contentions to
4 which no response is required. To the extent that a response is deemed required, Defendants
5 are without knowledge or information sufficient to form a belief as to the truth of the
6 allegations in this paragraph of the Complaint regarding Plaintiff's citizenship, the amount in
7 controversy, and the judicial district in which the asserted claims allegedly arose, and,
8 therefore, deny the same. However, Defendants admit that Plaintiff claims the parties are
9 diverse and that the amount in controversy exceeds \$75,000, exclusive of interests and costs.
10 Defendants deny the remaining allegations in this paragraph of the Complaint.

11 **Response to General Allegations**

12 2. Defendants admit that Plaintiff brought this civil action seeking monetary damages, but
13 deny that Plaintiff is entitled to any relief or damages. Defendants are without knowledge or
14 information sufficient to form a belief as to the truth of the allegations in this paragraph of the
15 Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same.
16 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
17 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law
18 authorized to prescribe drugs in accordance with its approval by the FDA. Defendants admit
19 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
20 developed, tested, marketed, co-promoted, and distributed Bextra® in the United States to be
21 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
22 with its approval by the FDA. Defendants state that Bextra® was and is safe and effective
23 when used in accordance with its FDA-approved prescribing information. Defendants state that
24 the potential effects of Bextra® were and are adequately described in its FDA-approved
25 prescribing information, which was at all times adequate and comported with applicable
26 standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® caused
27 Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the
28 Complaint.

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1 3. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
2 damage, and deny the remaining allegations in this paragraph of the Complaint.

3 4. Defendants deny the allegations in this paragraph of the Complaint.

4 5. Defendants deny the allegations in this paragraph of the Complaint.

5 6. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
6 damage, and deny the remaining allegations in this paragraph of the Complaint.

7 7. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
8 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
9 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
10 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
11 which developed, tested, marketed, co-promoted, and distributed Bextra® in the United States
12 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
13 accordance with their approval by the FDA. Defendants state that the allegations in this
14 paragraph of the Complaint regarding "successors in interest" are vague and ambiguous.
15 Defendants are without knowledge or information sufficient to form a belief as to the truth of
16 such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in
17 this paragraph of the Complaint.

18 8. Defendants admit that they do business in the State of Illinois. Defendants deny the
19 remaining allegations in this paragraph of the Complaint.

20 9. Defendants state that Bextra® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants state that the potential effects of
22 Bextra® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendants deny any wrongful conduct, deny committing a tort in the States of Illinois or
25 California, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining
26 allegations in this paragraph of the Complaint.

27 10. Defendants state that this paragraph of the Complaint contains legal contentions to
28 which no response is required. To the extent that a response is deemed required, Defendants

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1 state that Bextra® was and is safe and effective when used in accordance with its FDA-
2 approved prescribing information. Defendants state that the potential effects of Bextra® were
3 and are adequately described in its FDA-approved prescribing information, which was at all
4 times adequate and comported with applicable standards of care and law. Defendants deny any
5 wrongful conduct, deny committing a tort in the States of Illinois or California, deny that
6 Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph
7 of the Complaint.

8 **Response to Allegations Regarding Parties**

9 11. Defendants are without knowledge or information sufficient to form a belief as to the
10 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's citizenship and
11 whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny any wrongful
12 conduct, deny that Bextra® caused Plaintiff or Decedent injury or damage, and deny the
13 remaining allegations in this paragraph of the Complaint.

14 12. Defendants are without knowledge or information sufficient to form a belief as to the
15 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
16 Bextra®, and, therefore, deny the same. Defendants admit that Searle is a Delaware limited
17 liability company with its principal place of business in Illinois. Defendants admit that, during
18 certain periods of time, Bextra® was manufactured and packaged for Searle, which developed,
19 tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by
20 healthcare providers who are by law authorized to prescribe drugs in accordance with their
21 approval by the FDA. Defendants deny the remaining allegations in this paragraph of the
22 Complaint.

23 13. Defendants admit that Pharmacia is a Delaware corporation with its principal place of
24 business in New Jersey. Defendants admit that Pharmacia is registered to do and does business
25 in the State of Illinois. Defendants admit that Pharmacia may be served through its registered
26 agent. Defendants admit that, during certain periods of time, Pharmacia marketed and co-
27 promoted Bextra® in the United States, including Illinois, to be prescribed by healthcare
28 providers who are by law authorized to prescribe drugs in accordance with their approval by the

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1 FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

2 14. Defendants admit that Pfizer is a Delaware corporation with its principal place of
3 business in New York. Defendants admit that Pfizer is registered to do and does business in the
4 State of Illinois. Defendants admit that Pfizer may be served through its registered agent.
5 Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted
6 Bextra® in the United States, including Illinois, to be prescribed by healthcare providers who
7 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
8 Defendants deny the remaining allegations in this paragraph of the Complaint.

9 15. Defendants state that Bextra® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendants state that the potential effects of
11 Bextra® were and are adequately described in its FDA-approved prescribing information,
12 which was at all times adequate and comported with applicable standards of care and law.
13 Defendants deny any wrongful conduct, deny committing a tort in the States of Illinois or
14 California, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining
15 allegations in this paragraph of the Complaint.

16 16. Defendants are without knowledge or information sufficient to form a belief as to the
17 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
18 Bextra®, and, therefore, deny the same. Defendants admit that, during certain periods of time,
19 Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed
20 by healthcare providers who are by law authorized to prescribe drugs in accordance with their
21 approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was
22 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted, and
23 distributed Bextra® in the United States to be prescribed by healthcare providers who are by
24 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
25 deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the
26 remaining allegations in this paragraph of the Complaint.

27 **Response to Overview Allegations**

28 17. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®

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1 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
2 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants admit
3 that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra®
4 in the United States to be prescribed by healthcare providers who are by law authorized to
5 prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during
6 certain periods of time, Bextra® was manufactured and packaged for Searle, which developed,
7 tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by
8 healthcare providers who are by law authorized to prescribe drugs in accordance with their
9 approval by the FDA. Defendants state that Bextra® was and is safe and effective when used
10 in accordance with its FDA-approved prescribing information. Defendants state that the
11 potential effects of Bextra® were and are adequately described in its FDA-approved prescribing
12 information, which was at all times adequate and comported with applicable standards of care
13 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
14 paragraph of the Complaint.

18. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
19 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
20 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
21 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
22 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
23 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
24 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
25 effective when used in accordance with its FDA-approved prescribing information. Defendants
26 state that the potential effects of Bextra® were and are adequately described in its FDA-
27 approved prescribing information, which was at all times adequate and comported with
28 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
remaining allegations in this paragraph of the Complaint.

19. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®
20 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult

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1 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Plaintiff fails to
2 provide the proper context for the remaining allegations in this paragraph of the Complaint.
3 Defendants lack knowledge or information sufficient to form a belief as to the truth of such
4 allegations and, therefore, deny the same. Defendants deny the remaining allegations in this
5 paragraph of the Complaint.

6 20. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
7 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
8 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
9 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
10 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
11 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
12 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
13 paragraph of the Complaint.

14 21. Defendants state that Bextra® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Bextra® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra®
19 caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the
20 Complaint.

21 22. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
22 damage, and deny the remaining allegations in this paragraph of the Complaint.

23 23. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
24 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
25 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
26 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
27 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
28 be prescribed by healthcare providers who are by law authorized to prescribe drugs in

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1 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
2 paragraph of the Complaint.

3 24. Defendants are without knowledge or information sufficient to form a belief as to the
4 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
5 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and
6 effective when used in accordance with its FDA-approved prescribing information. Defendants
7 state that the potential effects of Bextra® were and are adequately described in its FDA-
8 approved prescribing information, which was at all times adequate and comported with
9 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
10 Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph
11 of the Complaint.

12 **Response to Factual Allegations**

13 25. Defendants state that, as stated in the FDA-approved labeling for Bextra®, “[t]he
14 mechanism of action is believed to be due to inhibition of prostaglandin synthesis primarily
15 through inhibition of cyclooxygenase-2 (COX-2). At therapeutic plasma concentrations in
16 humans valdecoxib does not inhibit cyclooxygenase-1 (COX-1).” Defendants state that
17 Bextra® was and is safe and effective when used in accordance with its FDA-approved
18 prescribing information. Plaintiff does not allege that Plaintiff used Celebrex® in this
19 Complaint. Nevertheless, Defendants state that Celebrex® was and is safe and effective when
20 used in accordance with its FDA-approved prescribing information. Defendants state that
21 Plaintiff fails to provide the proper context for the allegations in this paragraph of the
22 Complaint regarding Vioxx®, aspirin, and ibuprofen. Defendants therefore lack knowledge or
23 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny
24 the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

25 26. Defendants admit that Bextra® was approved by the FDA on November 16, 2001.
26 Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is
27 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid
28 arthritis, as well as for the treatment of primary dysmenorrhea. Defendants admit that, during

1 certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United
2 States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
3 accordance with their approval by the FDA. Defendants admit that, during certain periods of
4 time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed,
5 co-promoted and distributed Bextra® in the United States to be prescribed by healthcare
6 providers who are by law authorized to prescribe drugs in accordance with their approval by the
7 FDA. Defendants state that Bextra® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
9 this paragraph of the Complaint.

10 27. Defendants admit that Bextra® is in a class of drugs that is, at times, referred to as non-
11 steroidal anti-inflammatory drugs (“NSAIDS”). Defendants state that, as stated in the FDA-
12 approved labeling for Bextra®, “[t]he mechanism of action is believed to be due to inhibition of
13 prostaglandin synthesis primarily through inhibition of cyclooxygenase-2 (COX-2). At
14 therapeutic plasma concentrations in humans valdecoxib does not inhibit cyclooxygenase-1
15 (COX-1).” Defendants deny the remaining allegations in this paragraph of the Complaint.

16 28. Defendants state that Bextra® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants state that the potential effects of
18 Bextra® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
21 the Complaint.

22 29. Defendants state that Bextra® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Bextra® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
27 the Complaint.

28 30. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed

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1 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
2 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
3 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
4 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
5 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
6 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
7 effective when used in accordance with its FDA-approved prescribing information. Defendants
8 state that the potential effects of Bextra® were and are adequately described in its FDA-
9 approved prescribing information, which was at all times adequate and comported with
10 applicable standards of care and law. Defendants deny the remaining allegations in this
11 paragraph of the Complaint.

12 31. Defendants state that Bextra® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Bextra® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
17 the Complaint.

18 32. Defendants state that Bextra® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants state that the potential effects of
20 Bextra® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
23 the Complaint.

24 33. Defendants state that Bextra® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendants state that the potential effects of
26 Bextra® were and are adequately described in its FDA-approved prescribing information,
27 which was at all times adequate and comported with applicable standards of care and law.
28 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of

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1 the Complaint.

2 34. Defendants state that the referenced studies speak for themselves and respectfully refer
3 the Court to the studies for their actual language and text. Any attempt to characterize the
4 studies is denied. Defendants state that Bextra® was and is safe and effective when used in
5 accordance with its FDA-approved prescribing information. Defendants state that the potential
6 effects of Bextra® were and are adequately described in its FDA-approved prescribing
7 information, which was at all times adequate and comported with applicable standards of care
8 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
9 paragraph of the Complaint.

10 35. Defendants state that Bextra® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendants state that the potential effects of
12 Bextra® were and are adequately described in its FDA-approved prescribing information,
13 which was at all times adequate and comported with applicable standards of care and law.
14 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
15 the Complaint.

16 36. Defendants admit that the sale of Bextra® was voluntarily suspended in the U.S. market
17 as of April 7, 2005. Defendants admit that, during certain periods of time, Pfizer and
18 Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by
19 healthcare providers who are by law authorized to prescribe drugs in accordance with their
20 approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was
21 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and
22 distributed Bextra® in the United States to be prescribed by healthcare providers who are by
23 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
24 state that Bextra® was and is safe and effective when used in accordance with its FDA-
25 approved prescribing information. Defendants state that the potential effects of Bextra® were
26 and are adequately described in its FDA-approved prescribing information, which was at all
27 times adequate and comported with applicable standards of care and law. Defendants deny any
28 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

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1 37. Defendants are without knowledge or information sufficient to form a belief as to the
2 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
3 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and
4 effective when used in accordance with its FDA-approved prescribing information. Defendants
5 state that the potential effects of Bextra® were and are adequately described in its FDA-
6 approved prescribing information, which was at all times adequate and comported with
7 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
8 remaining allegations in this paragraph of the Complaint.

9 **Response to First Cause of Action: Strict Liability – Failure to Warn**

10 38. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
11 Complaint as if fully set forth herein.

12 39. Defendants state that Bextra® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Bextra® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
17 allegations in this paragraph of the Complaint.

18 40. Defendants state that this paragraph of the Complaint contains legal contentions to
19 which no response is required. To the extent that a response is deemed required, Defendants
20 admit that they had duties as are imposed by law but deny having breached such duties.
21 Defendants are without knowledge or information sufficient to form a belief as to the truth of
22 the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
23 and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective
24 when used in accordance with its FDA-approved prescribing information. Defendants state that
25 the potential effects of Bextra® were and are adequately described in its FDA-approved
26 prescribing information, which was at all times adequate and comported with applicable
27 standards of care and law. Defendants deny the remaining allegations in this paragraph of the
28 Complaint.

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1 41. Defendants are without knowledge or information sufficient to form a belief as to the
2 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
3 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and
4 effective when used in accordance with its FDA-approved prescribing information. Defendants
5 state that the potential effects of Bextra® were and are adequately described in its FDA-
6 approved prescribing information, which was at all times adequate and comported with
7 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
8 Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this
9 paragraph of the Complaint, including all subparts.

10 42. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
12 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and
13 effective when used in accordance with its FDA-approved prescribing information. Defendants
14 state that the potential effects of Bextra® were and are adequately described in its FDA-
15 approved prescribing information, which was at all times adequate and comported with
16 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
17 Bextra® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the
18 Complaint.

19 43. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
20 damage, and deny the remaining allegations in this paragraph of the Complaint.

21 44. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
22 damage, and deny the remaining allegations in this paragraph of the Complaint.

23 45. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
24 damage, and deny the remaining allegations in this paragraph of the Complaint.

25 46. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
26 damage, and deny the remaining allegations in this paragraph of the Complaint.

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Response to Second Cause of Action:

Strict Products Liability – Defective Design

47. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

48. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

20 49. Defendants are without knowledge or information sufficient to form a belief as to the
21 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
22 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and
23 effective when used in accordance with its FDA-approved prescribing information. Defendants
24 state that the potential effects of Bextra® were and are adequately described in its FDA-
25 approved prescribing information, which was at all times adequate and comported with
26 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
27 Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this
28 paragraph of the Complaint, including all subparts.

1 50. Defendants are without knowledge or information sufficient to form a belief as to the
2 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
3 Bextra®, and, therefore, deny the same. Defendants admit that, during certain periods of time,
4 Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed
5 by healthcare providers who are by law authorized to prescribe drugs in accordance with their
6 approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was
7 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and
8 distributed Bextra® in the United States to be prescribed by healthcare providers who are by
9 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
10 state that, in the ordinary case, Bextra® was expected to reach users and consumers without
11 substantial change from the time of sale. Defendants deny any wrongful conduct, deny that
12 Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this
13 paragraph of the Complaint.

14 51. Defendants are without knowledge or information sufficient to form a belief as to the
15 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
16 Bextra®, and, therefore, deny the same. Defendants deny the remaining allegations in this
17 paragraph of the Complaint.

18 52. Defendants state that Bextra® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants state that the potential effects of
20 Bextra® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably
23 dangerous, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining
24 allegations in this paragraph of the Complaint.

25 **Response to Third Cause of Action: Negligence**

26 53. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
27 Complaint as if fully set forth herein.

28 54. Defendants state that this paragraph of the Complaint contains legal contentions to

1 which no response is required. To the extent that a response is deemed required, Defendants
2 admit that they had duties as are imposed by law but deny having breached such duties.
3 Defendants state that Bextra® was and is safe and effective when used in accordance with its
4 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
5 were and are adequately described in its FDA-approved prescribing information, which was at
6 all times adequate and comported with applicable standards of care and law. Defendants deny
7 the remaining allegations in this paragraph of the Complaint.

8 55. Defendants state that Bextra® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendants state that the potential effects of
10 Bextra® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
13 the Complaint.

14 56. Defendants are without knowledge or information sufficient to form a belief as to the
15 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
16 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and
17 effective when used in accordance with its FDA-approved prescribing information. Defendants
18 state that the potential effects of Bextra® were and are adequately described in its FDA-
19 approved prescribing information, which was at all times adequate and comported with
20 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
21 Bextra® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the
22 Complaint.

23 57. Defendants are without knowledge or information sufficient to form a belief as to the
24 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
25 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and
26 effective when used in accordance with its FDA-approved prescribing information. Defendants
27 state that the potential effects of Bextra® were and are adequately described in its FDA-
28 approved prescribing information, which was at all times adequate and comported with

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1 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
2 Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph
3 of the Complaint.

4 **Response to Fourth Cause of Action: Breach of Implied Warranty**

5 58. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
6 Complaint as if fully set forth herein.

7 59. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
9 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and
10 effective when used in accordance with its FDA-approved prescribing information. Defendants
11 state that the potential effects of Bextra® were and are adequately described in its FDA-
12 approved prescribing information, which was at all times adequate and comported with
13 applicable standards of care and law. Defendants admit that they provided FDA-approved
14 prescribing information regarding Celebrex® and Bextra®. Defendants deny the remaining
15 allegations in this paragraph of the Complaint.

16 60. Defendants deny the allegations in this paragraph of the Complaint.

17 61. Defendants state that Bextra® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Bextra® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
22 the Complaint.

23 62. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
24 damage, and deny the remaining allegations in this paragraph of the Complaint.

25 **Response to Fifth Cause of Action: Breach of Express Warranty**

26 63. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
27 Complaint as if fully set forth herein.

28 64. Defendants state that Bextra® was and is safe and effective when used in accordance

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1 with its FDA-approved prescribing information. Defendants state that the potential effects of
2 Bextra® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendants admit that they provided FDA-approved prescribing information regarding
5 Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

6 65. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
8 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and
9 effective when used in accordance with its FDA-approved prescribing information. Defendants
10 state that the potential effects of Bextra® were and are adequately described in its FDA-
11 approved prescribing information, which was at all times adequate and comported with
12 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
13 remaining allegations in this paragraph of the Complaint.

14 66. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
15 damage, and deny the remaining allegations in this paragraph of the Complaint.

16 **Response to Sixth Cause of Action: Deceit by Concealment**

17 67. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
18 Complaint as if fully set forth herein.

19 68. Defendants state that Bextra® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Bextra® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
24 the Complaint.

25 69. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
26 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
27 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
28 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,

1 which developed, tested, marketed, co-promoted, and distributed Bextra® in the United States
2 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
3 accordance with their approval by the FDA. Defendants state that Bextra® was and is and
4 effective when used in accordance with its FDA-approved prescribing information. Defendants
5 state that the potential effects of Bextra® were and are adequately described in its FDA-
6 approved prescribing information, which was at all times adequate and comported with
7 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
8 Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph
9 of the Complaint.

10 70. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
12 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is and effective
13 when used in accordance with its FDA-approved prescribing information. Defendants state that
14 the potential effects of Bextra® were and are adequately described in its FDA-approved
15 prescribing information, which was at all times adequate and comported with applicable
16 standards of care and law. Defendants deny any wrongful conduct and deny the remaining
17 allegations in this paragraph of the Complaint.

18 71. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
19 damage, and deny the remaining allegations in this paragraph of the Complaint.

20 **Response to Seventh Cause of Action: Negligent Misrepresentation**

21 72. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
22 Complaint as if fully set forth herein.

23 73. Defendants state that Bextra® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Bextra® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
28 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law

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1 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
2 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
3 developed, tested, marketed, co-promoted, and distributed Bextra® in the United States to be
4 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
5 with their approval by the FDA. Defendants deny any wrongful conduct and deny the
6 remaining allegations in this paragraph of the Complaint.

7 74. Defendants state that Bextra® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Bextra® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
12 the Complaint.

13 75. Defendants are without knowledge or information sufficient to form a belief as to the
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
15 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and
16 effective when used in accordance with its FDA-approved prescribing information. Defendants
17 state that the potential effects of Bextra® were and are adequately described in its FDA-
18 approved prescribing information, which was at all times adequate and comported with
19 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
20 Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph
21 of the Complaint.

22 76. Defendants deny any wrongful conduct and deny the remaining allegations in this
23 paragraph of the Complaint.

24 77. Defendants are without knowledge or information sufficient to form a belief as to the
25 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
26 Bextra®, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the
27 remaining allegations in this paragraph of the Complaint.

28 78. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or

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1 damage, and deny the remaining allegations in this paragraph of the Complaint.

2 **Response to Allegations Regarding Punitive Damages**

3 79. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
4 Complaint as if fully set forth herein.

5 80. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
6 damage, and deny the remaining allegations in this paragraph of the Complaint.

7 81. Defendants are without knowledge or information sufficient to form a belief as to the
8 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
9 Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and
10 effective when used in accordance with its FDA-approved prescribing information. Defendants
11 state that the potential effects of Bextra® were and are adequately described in its FDA-
12 approved prescribing information, which was at all times adequate and comported with
13 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
14 Bextra® is defective or unreasonably dangerous, deny that Bextra® caused Plaintiff injury or
15 damage, and deny the remaining allegations in this paragraph of the Complaint.

16 82. Defendants state that Bextra® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants state that the potential effects of
18 Bextra® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably
21 dangerous, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining
22 allegations in this paragraph of the Complaint.

23 83. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
24 damage, and deny the remaining allegations in this paragraph of the Complaint.

25 Answering the unnumbered paragraph following Paragraph 83 of the Complaint,
26 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage,
27 and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

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III.

GENERAL DENIAL

Defendants deny all allegations and/or legal conclusions set forth in Plaintiff's Complaint that have not been previously admitted, denied, or explained.

IV.

AFFIRMATIVE DEFENSES

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiff to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Bextra® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Bextra® was at all times in compliance with applicable federal law. Plaintiff's causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the

1 applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

2 **Sixth Defense**

3 6. Plaintiff's action is barred by the statute of repose.

4 **Seventh Defense**

5 7. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the
6 Complaint, the same were caused by the negligence or fault of the Plaintiff and Plaintiff's
7 damages, if any, are barred or reduced by the doctrines of comparative fault and contributory
8 negligence and by the failure to mitigate damages.

9 **Eighth Defense**

10 8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or
11 omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the
12 part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not
13 liable in any way.

14 **Ninth Defense**

15 9. The acts and/or omissions of unrelated third parties as alleged constituted independent,
16 intervening causes for which Defendants cannot be liable.

17 **Tenth Defense**

18 10. Any injuries or expenses incurred by Plaintiff were not caused by Bextra®, but were
19 proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act
20 of God.

21 **Eleventh Defense**

22 11. Defendants affirmatively deny that they violated any duty owed to Plaintiff.

23 **Twelfth Defense**

24 12. A manufacturer has no duty to warn patients or the general public of any risk,
25 contraindication, or adverse effect associated with the use of a prescription medical product.
26 Rather, the law requires that all such warnings and appropriate information be given to the
27 prescribing physician and the medical profession, which act as a "learned intermediary" in
28 determining the use of the product. Bextra® is a prescription medical product, available only

1 on the order of a licensed physician. Bextra® provided an adequate warning to Plaintiff's
2 treating and prescribing physicians.

3 **Thirteenth Defense**

4 13. The product at issue was not in a defective condition or unreasonably dangerous at the
5 time it left the control of the manufacturer or seller.

6 **Fourteenth Defense**

7 14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit
8 for its intended use and the warnings and instructions accompanying Bextra® at the time of the
9 occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

10 **Fifteenth Defense**

11 15. Plaintiff's causes of action are barred in whole or in part by the lack of a defect as the
12 Bextra® allegedly ingested by Plaintiff was prepared in accordance with the applicable
13 standard of care.

14 **Sixteenth Defense**

15 16. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the
16 Complaint, the same were caused by the unforeseeable alteration, change, improper handling,
17 abnormal use, or other unforeseeable misuse of Bextra® by persons other than Defendants or
18 persons acting on its behalf after the product left the control of Defendants.

19 **Seventeenth Defense**

20 17. Plaintiff's alleged damages were not caused by any failure to warn on the part of
21 Defendants.

22 **Eighteenth Defense**

23 18. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent
24 conditions unrelated to Bextra®.

25 **Nineteenth Defense**

26 19. Plaintiff knew or should have known of any risk associated with Bextra®; therefore, the
27 doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

Twenty-third Defense

23. Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages in this case would violate Defendants' rights to procedural due process under the Fourteenth Amendment of the United States Constitution and the Constitutions of the States of Illinois and California, and would additionally violate Defendants' right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiff failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution and the Constitutions of the States of Illinois and California. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5)

1 permits jury consideration of net worth or other financial information relating to Defendants;
2 (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict
3 review of any punitive damages awards; (7) lacks constitutionally sufficient standards for
4 appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court
5 precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1
6 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North*
7 *America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*,
8 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design,
and marketing of Bextra®, if any, used in this case, included adequate warnings and
instructions with respect to the product's use in the package insert and other literature, and
conformed to the generally recognized, reasonably available, and reliable state of the
knowledge at the time the product was marketed.

Fortieth Defense

16 40. The claims asserted in the Complaint are barred because Bextra® was designed, tested,
17 manufactured and labeled in accordance with the state-of-the-art industry standards existing at
18 the time of the sale.

Forty-first Defense

20 41. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information
21 and belief, such injuries and losses were caused by the actions of persons not having real or
22 apparent authority to take said actions on behalf of Defendants and over whom Defendants had
23 no control and for whom Defendants may not be held accountable.

Forty-second Defense

25 42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra®
26 was not unreasonably dangerous or defective, was suitable for the purpose for which it was
27 intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiff.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiff would have taken Bextra® even if the product labeling contained the information that Plaintiff contends should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Bextra® outweighed its risks.

Fiftieth Defense

50. Plaintiff's damages, if any, are barred or limited by the payments received from

1 collateral sources.

2 **Fifty-first Defense**

3 51. Defendants' liability, if any, can only be determined after the percentages of
4 responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if
5 any, are determined. Defendants seek an adjudication of the percentage of fault of the
6 claimants and each and every other person whose fault could have contributed to the alleged
7 injuries and damages, if any, of Plaintiff.

8 **Fifty-second Defense**

9 52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the
10 common law gives deference to discretionary actions by the United States Food and Drug
11 Administration under the Federal Food, Drug, and Cosmetic Act.

12 **Fifty-third Defense**

13 53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is
14 comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act
15 ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff's
16 claims conflict with the FDCA, with the regulations promulgated by FDA to implement the
17 FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations,
18 and with the specific determinations by FDA specifying the language that should be used in the
19 labeling accompanying Bextra®. Accordingly, Plaintiff's claims are preempted by the
20 Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the
21 United States.

22 **Fifty-fourth Defense**

23 54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity
24 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

25 **Fifty-fifth Defense**

26 55. Defendants state on information and belief that the Complaint and each purported cause
27 of action contained therein is barred by the statutes of limitations contained in California Code
28 of Civil Procedure §§ 335.1 and 338 and former § 340(3), such other statutes of limitation as

1 may apply.

2 **Fifty-sixth Defense**

3 56. Defendants state on information and belief that any injuries, losses, or damages suffered
 4 by Plaintiff were proximately caused, in whole or in part, by the negligence or other actionable
 5 conduct of persons or entities other than Defendants. Therefore, Plaintiff's recovery against
 6 Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

7 **Fifty-seventh Defense**

8 57. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of
 9 Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil
 10 Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive
 11 damages is also barred under California Civil Code § 3294(b).

12 **Fifty-eighth Defense**

13 58. The claims asserted in the Complaint are barred, in whole or in part, because
 14 Defendants did not violate the Illinois Consumer Fraud and Deceptive Business Practice Act,
 15 815 ILCS 505/1 et seq., and/or this Act is not applicable to this matter and/or to this Plaintiff.

16 **Fifty-ninth Defense**

17 59. Defendants reserve the right to supplement their assertion of defenses as they continue
 18 with their factual investigation of Plaintiff's claims.

19 **V.**

20 **PRAYER**

21 WHEREFORE, Defendants pray for judgment as follows:

22 1. That Plaintiff takes nothing from Defendants by reason of the Complaint;
 23 2. That the Complaint be dismissed;
 24 3. That Defendants be awarded their costs for this lawsuit;
 25 4. That the trier of fact determine what percentage of the combined fault or other liability
 26 of all persons whose fault or other liability proximately caused Plaintiff's alleged
 27 injuries, losses or damages is attributable to each person;
 28 5. That any judgment for damages against Defendants in favor of Plaintiff be no greater

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1 than an amount which equals their proportionate share, if any, of the total fault or other
2 liability which proximately caused Plaintiff's injuries and damages; and

3 6. That Defendants have such other and further relief as the Court deems appropriate.

4 April 24, 2008

5 GORDON & REES LLP

6 By: _____/s/_____

7
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15 April 24, 2008

16 TUCKER ELLIS & WEST LLP

17 By: _____/s/_____

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26 CORPORATION, AND G.D. SEARLE
27 LLC

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1 **JURY DEMAND**

2 Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC, hereby demand a
3 trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil
4 Procedure.

5 April 24, 2008

GORDON & REES LLP

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7 By: _____/s/_____

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April 24, 2008

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